K130198

510(k) Summary

Submitter: Mike Adams, Q1D G/F Kaiser 3rd Phase, 18 Man Lok Street, Hung Hom, Kowloon, Hong Kong.

OCT 2 1 2013

I. Classification Names: Porcelain powder for Clinical use, EIH

II. Regulation Number: CFR 872.6660

III. Common/ Usual Name: Zirconia disc, porcelain material for dental restoration

IV. Proprietary Names: Neo Denta Zirconia

V. Establishment Registration Number: In Process

VI. Device description: Neo Denta Zirconia is a partially sintered zirconia disc, which is yttrium oxide stabilized zirconium dioxide. The disc can be milled into various shapes of prostheses. A CAD/CAM system can be used to produce the prostheses needed from the blank. Neo Denta Zirconia provides an alternate to the gold, porcelain, ceramics and other types of material used in the dental laboratories for dental restoration.

VII. Indication for Use: Remedial Blanks for the Fabrication of Dental Restoration

VIII. Technological Characteristics: Since Neo Denta Zirconia is actually relabeled product of the predicate device, Sagemax Z-Blank, Neo Denta Zirconia shares the same technological characteristic with the product of Sagemax. The dimensions, the material, the chemical composition and all other properties of Neo Denta Zirconia are the same compared to Sagemax Z-Blank. The only difference is the design of the packaging material.

IX. Nonclinical Testing: Particle size was measured by laser scanning, Energy Dispersive Spectrometry (EDS) & X-ray EV for chemical composition, microstructure, surface condition and abnormalities, 1-CR value was determined using the Xrite Color i7 and UV Spectrophotometer, and an Autograph strength test machine for flexural strength and toughness, by determining breakage points in 3 point, 4 point and biaxial flexural tests.

X. Clinical Testing: Clinical testing was not performed for Neo Denta Zirconia since there is no difference in technological characteristics when compared to its predicate.

XI. Substantial Equivalence: Neo Denta Zirconia is the relabeled product of Sagemax Z-Blank, which is cleared by the 510(k) process with the number Z062695, and with the same intended use with Sagemax Z-Blank. Therefore, Neo Denta Zirconia is substantially equivalent in safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2013

Neo Group Ltd.
C/O Mr. Mike Adams
Director of R&D and Manufacturing
Q1D, G/F, Kaiser Estate 3rd Phase
18 Man Lok Street, Hung Hom
Kowloon, Hong Kong
REPUBLIC OF CHINA

Re: K130198
Trade/Device Name: Neo Denta Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: July 24, 2013
Received: July 29, 2013

Dear Mr. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130198

Indication for Use Statement

510(k) Number (if known): NA

Device Name: Neo Denta zirconia

Indications For Use:
Remedial Blanks for the Fabrication of Dental Restoration

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner -S
Mary S. Runner -S
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